DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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PDA/FDA Viral Clearance Forum; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Parenteral Drug Association (PDA)/FDA Viral Clearance Forum." The topic to be discussed is viral clearance for biologics.

Date and Time: The public workshop will be held on October 1, 2001, from 8 a.m. to 4:30 p.m., October 2, 2001, from 8:30 a.m. to 4:30 p.m., and October 3, 2001, from 8:30 a.m. to 3 p.m.

Location: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD.

Contact:

For information regarding this notice: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, FAX 301–594–1944, e-mail: gearyn@cber.fda.gov.

For information regarding the public workshop: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3841, FAX 301–827–3843, e-mail: Whelan@cber.fda.gov, or Leslie Zeck, PDA, Inc., 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814, 301–986–0293, FAX 301–986–0296, e-mail: zeck@pda.org.

If you need special accommodations due to a disability, please contact Leslie Zeck (address above) at least 7 days in advance.

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Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax number), and registration fee to PDA, Inc., P.O. Box 79465, Baltimore, MD 21279–3465 by Monday, September 24, 2001. You may also register with PDA, Inc., by phone at 301–986–0293 or fax at 301–986–0296 with your credit card.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. You may obtain registration forms from PDA, Inc., (address above) or from the FDA Internet at http://www.fda.gov/cber/meetings.htm.

SUPPLEMENTARY INFORMATION: The public workshop is being cosponsored by FDA, CBER, and PDA, Inc. The goals of the public workshop are to discuss: (1) Current and new viral removal technologies; (2) issues related to the reuse of chromatographic columns with an emphasis on viral clearance requirements; (3) current opinions on the need to standardize quality attributes of viral preparations used as controls in spiking and infectivity assays; (4) current methods used to standardize or validate traditional infectivity assays; (5) implementation and acceptability of polymerase chain reaction (PCR), PCR enhanced reverse transcriptase, and real-time PCR-based viral assays, standardization and validation of these new assays, and (6) the potential of and issues

related to bracket/matrix studies defining generic virus inactivation conditions. FDA expects that participation in this workshop will provide manufacturers a regulatory perspective on viral clearance and facilitate product development and approval.

Dated: 9/10/01

September 10, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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